



Billing Code 4410-09-M

DEPARTMENT OF JUSTICE  
Drug Enforcement Administration  
Importer of Controlled Substances  
Notice of Application  
Mylan Pharmaceuticals, Inc.

Pursuant to Title 21 Code of Federal Regulations  
1301.34 (a), this is notice that on March 8, 2013, Mylan  
Pharmaceuticals, Inc., 3711 Collins Ferry Road, Morgantown,  
West Virginia 26505, made application to the Drug  
Enforcement Administration (DEA) to be registered as an  
importer of the following basic classes of controlled  
substances:

Drug	Schedule
Amphetamine (1100)	II
Lisdexamfetamine (1205)	II
Methylphenidate (1724)	II
Pentobarbital (2270)	II
Oxycodone (9143)	II
Hydromorphone (9150)	II
Hydrocodone (9193)	II
Levorphanol (9220)	II

Drug	Schedule
Morphine (9300)	II
Oxymorphone (9652)	II
Remifentanil (9739)	II
Fentanyl (9801)	II

The company plans to import the listed controlled substances in finished dosage form (FDF) from foreign sources for analytical testing and clinical trials in which the foreign FDF will be compared to the company's own domestically-manufactured FDF. This analysis is required to allow the company to export domestically-manufactured FDF to foreign markets.

Any bulk manufacturer who is presently, or is applying to be, registered with DEA to manufacture such basic classes of controlled substances listed in schedule II, which falls under the authority of section 1002(a)(2)(B) of the Act 21 USC § 952(a)(2)(B) may, in the circumstances set forth in 21 USC § 958(i), file comments or objections to the issuance of the proposed registration and may, at the same time, file a written request for a hearing on such application pursuant to 21 CFR § 1301.43 and in such form as prescribed by 21 CFR § 1316.47.

Any such written comments or objections should be addressed, in quintuplicate, to the Drug Enforcement Administration, Office of Diversion Control, Federal Register Representative (ODL), 8701 Morrisette Drive, Springfield, Virginia 22152; and must be filed no later than [INSERT DATE 30 DAYS FROM DATE OF PUBLICATION].

This procedure is to be conducted simultaneously with, and independent of, the procedures described in 21 CFR § 1301.34(b), (c), (d), (e), and (f). As noted in a previous notice published in the Federal Register on September 23, 1975, 40 FR 43745-46, all applicants for registration to import a basic classes of any controlled substances in schedules I or II are, and will continue to be, required to demonstrate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, that the requirements for such registration pursuant to 21 USC § 958(a); 21 USC § 823(a); and 21 CFR § 1301.34(b), (c), (d), (e), and (f) are satisfied.

Joseph T. Rannazzisi  
Deputy Assistant Administrator  
Office of Diversion Control  
Drug Enforcement Administration

DATED: June 18, 2013

[FR Doc. 2013-15587 Filed 06/28/2013 at 8:45 am;  
Publication Date: 07/01/2013]